IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 12-00362-CV-W-GAF**
	)	
1,149 FOUR OUNCE ROUND METAL TINS, MORE OR LESS, OF AN ARTICLE OF DRUG, LABELED IN PART "CHICKWEED HEALING SALVE" "USAGE: GOOD FOR SKIN DISORDERS" "MADE BY: S.A.E.G.", et al.,	)	
	)	
Defendants.	)	

AMENDED ORDER

Presently before the Court is Plaintiff the United States of America's (the "Government") Motion for Summary Judgment pursuant to Federal Rule of Civil Procedure 56. (Doc. # 50). Claimant Samuel A. Girod ("Claimant") opposes. (Doc. # 71). For the reasons set forth below, the Government's Motion is GRANTED.

DISCUSSION

I. FACTS

The Government's Amended Complaint sought the condemnation and forfeiture under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act"), of Defendants 1,149 Four ounce round metal tins, more or less, of an article of drug, labeled in part, "CHICKWEED HEALING SALVE," "Usage: Good for skin disorders," "Made by: S.A.E.G." (hereinafter "Chickweed Healing Salve"); 224 Two ounce round metal tins, more or less, of an article of drug, labeled in part, "TO-MOR-GONE," "(Black Salve)," "Ingredients: Blood Root"

(hereinafter "To-Mor-Gone"); 316 One third fluid ounce glass bottles, more or less, of an article of drug, labeled in part, "R.E.P.," "For sinus infection," "Made by: S.A.E.G." (hereinafter "R.E.P."); and all other quantities of the above articles of drug, in any size and type of container, whether labeled or unlabeled that are located anywhere on the premises of Notions-n-Things, Distribution, 20497 Hwy 65, Bogard, MO, and which are labeled or otherwise determined to have originated outside the State of Missouri (collectively "Defendants in rem"). (Doc. # 27). Additionally, the Government sought a statutory injunction under the Act to enjoin Claimant from violating the Act. (*Id.*).

Starting in 2001, the Federal Food and Drug Administration (the "FDA") began inspecting Claimant's manufacturing operation. (Declaration of Mark E. Parmon ("Parmon Decl.") ¶ 8). FDA investigators reviewed the labeling of, among other products, the Chickweed Healing Salve. (*Id.*). After reviewing the labeling, investigators explained to Claimant that his labeling contained drug claims and did not conform to the Act. (*Id.*). The FDA continued its investigation, and in 2005 FDA inspectors again explained to Claimant that his products were unapproved new drugs. (*Id.* ¶ 11). Again in 2012, FDA inspectors explained to Claimant that his labeling contained drug claims. (*Id.* ¶ 13). The FDA's final inspection was in March 2012. (*Id.* ¶ 14).

During their investigation, FDA inspectors collected labeling for Defendants in rem. The Chickweed Healing Salve labels collected contained the following claim: "Good for skin disorders. Dry skin, cuts, burns, draws, and poison ivy." (Declaration of Tamara J. Umscheid ("Umscheid Decl.") ¶ 5). Additionally, sales pamphlets for Chickweed Healing Salve, which included mail-order forms, contained testimonials about the product, such as:

> I had skin cancer removed 2 times from my face. The 3rd time it came back, I decided to use Chickweed Healing Salve. Within 2 weeks, it was gone. I also

> used it on my leg and ankle that was swollen. It went down and the soreness left also. Thank you for your help.

(*Id.*).

The labels attached to To-Mor-Gone stated it was a "Black Salve." (*Id.* ¶ 6). The sales pamphlet accompanying To-Mor-Gone stated it was "Good for Warts, Moles and Tumors." (*Id.*). The sales pamphlet additionally included a testimonial stating:

> I had a mole on the side of my neck. Doctors felt like it could be Cancer and wanted to remove it, but I put on TO-MOR-GONE every day and put a band aid over it. In about 2 ½ weeks it came off, left no scar, never bled. I am thankful to have TO-MOR-GONE.

(*Id.*).

The label attached to a bottle of R.E.P. stated "For sinus infection, put on forehead & cheeks. For breath freshener put drop on tongue." (*Id.* ¶ 7). The labeling did not include a list of ingredients. (*Id.*). The sales pamphlet accompanying R.E.P. stated, "R.E.P. is good for sinus infections, cold symptoms, sore throat, etc…and is also an active breath freshener." (*Id.*). Additionally, the sales pamphlet contained testimonials, such as:

> I had a sinus infection for over a year. I was using 3 to 4 nasal spray containers a week. I finally went and got R.E.P. FROM Sam. I applied as he told me to and didn't use a nasal spray. I drained a lot of ugly junk the next day and my sinuses cleared up immediately.

(*Id.*).

To support its contention that Defendants in rem were not generally recognized as safe and effective, the Government introduced the declaration of Dr. Charles E. Lee ("Dr. Lee"), the FDA's Senior Medical Advisor in the Office of Unapproved Drugs and Labeling Compliance. Dr. Lee attested there were no published adequate and well-controlled studies of any kind concerning Chickweed Healing Salve, To-Mor-Gone, or R.E.P. (Declaration of Charles E. Lee, M.D. ("Lee Decl.") ¶ 19). Dr. Lee further attested that, in his opinion, Defendants in rem were

not generally recognized as safe and effective. (*Id.* ¶ 20). Additionally, Dr. Lee attested that there were no FDA-approved drug applications for Defendants in rem. (*Id.* ¶ 22).

The Government introduced further evidence concerning the safety of To-Mor-Gone specifically. According to Dr. Jane E. Liedtka ("Dr. Liedtka"), a Medical Officer for the FDA, the term "Black Salve" refers to "a number of different compounds containing escharotic (caustic) agents as their primary ingredients." (Declaration of Jane E. Liedtka, M.D. ("Liedtka Decl.") ¶ 13). Dr. Liedtka further attested that "escharotic agents like black salves are caustic, corrosive substances that produce a thick coagulated crust (an eschar) and subsequently a scar on the area to which the escharotic agent(s) is applied." (*Id.* ¶ 15). According to Dr. Liedtka, case reports showed that scarring caused by escharotic agents masked the recurrence of skin cancer, causing delay in treatment and appropriate therapy, and, in at least one (1) case, death. (*Id.* ¶ 16). An additional risk associated with escharotic agents is the destruction of normal tissue surrounding the treated area. (*Id.* ¶ 17). In some cases, "the topical application of escharotic agents to treat skin cancer has resulted in the complete loss of the nasal ala (area of the external nose that surrounds the nostril) or mutilation of tissue to the point of bone exposure." (*Id.*). Dr. Liedtka attested that topical application of To-Mor-Gone "could result in scarring and/or mutilation of the area to which the product is applied." (Liedtka Decl. ¶ 19).

In response, Claimant argued that Chickweed Healing Salve was generally recognized as safe and effective. (Doc. # 71, p. 15). In support of his contention, Claimant pointed to the declaration of Dr. Shaw T. Chen ("Dr. Chen"), Team Leader for the Botanical Review Team and Deputy Director of the Office of Drug Evaluation IV for the FDA. Dr. Chen stated in a report that:

> Nevertheless, all the individual herbs in Chickweed Healing Salve have previous human use and several are also considered to be spices or food items, such as

> chickweed, mint, rosemary, and lavender. These plants are generally safe when used moderately in raw herb forms. Concentrated extracts or essential oils could be toxic even at much lower doses than the herb themselves.

(Declaration of Shaw T. Chen, M.D. ("Shaw Decl."), Ex. B, p. 6). Claimant additionally pointed to statements he made in an affirmation that his products "[were] simply raw materials [mixed] by cold infusion together with no chemical additives of any kind." (Affirmation of Samuel A. Girod ("Girod Affirm.") ¶ 6).

The Government also introduced evidence that Defendants in rem had been shipped in interstate commerce or had components shipped in interstate commerce. According to the Government, Claimant's manufacturing operation was located at his residence in Owingsville, Kentucky and the Government seized Defendants in rem in Bogard, Missouri. (Parmon Decl. ¶ 3; Umscheid Decl. ¶ 10). Moreover, Claimant bought raw ingredients in interstate commerce, including beeswax from West Babylon, New York, and rosemary, eucalyptus, peppermint, and lavender from Mishawaka, Indiana. (Parmon Decl. ¶ 14).

II. LEGAL STANDARD

Summary judgment should be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Summary judgment is appropriate if the evidence, viewed in the light most favorable to the [nonmovant] and giving [the nonmovant] the benefit of all reasonable inferences, shows there are no genuine issues of material fact and [the movant] is entitled to judgment as a matter of law." *Price v. N. States Power Co.*, 664 F.3d 1186, 1191 (8th Cir. 2011) (citation omitted). "Once the moving party has made and supported their motion, the nonmoving party must proffer admissible evidence demonstrating a genuine dispute as to a material fact." *Holden v. Hirner*, 663 F.3d 336, 340 (8th Cir. 2011) (citation omitted). Summary judgment should not be granted if a reasonable jury could find for the nonmoving party. *Woodsmith*

Publ'g Co. v. Meredith Corp., 904 F.2d 1244, 1247 (8th Cir. 1990) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

III. ANALYSIS

The Government seeks two (2) things in this action. (Doc. # 51, p. 7). First, pursuant to 21 U.S.C. § 334, the Government moves the Court to condemn Defendants in rem because such articles are unapproved new drugs and misbranded drugs. (*Id.*). Second, pursuant to 21 U.S.C. § 332, the Government moves the Court to enjoin Claimant from continuing to violate the Act by introducing and delivering for introduction into interstate commerce misbranded and unapproved new drugs and by misbranding drugs while such drugs are held for sale after shipment of their components in interstate commerce. (*Id.*). Accordingly, the Court must determine whether Defendants in rem are: 1) drugs, 2) new, 3) unapproved, and 4) misbranded. The Court must further determine whether condemnation of Defendants in rem is appropriate and whether an injunction should issue.

A. Condemnation of Defendants in rem

Under 21 U.S.C. § 334, any drug that is an unapproved new drug or misbranded under the Act shall be condemned if the drug was introduced into interstate commerce or held for sale after shipment in interstate commerce.

1. Unapproved New Drugs

i. Whether Defendants in rem are "drugs"

Under the Act, a product is a "drug" if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man [or] intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(B),(C). Accordingly, whether a product is a drug depends on the product's intended use. *United States v. Articles of Drug for Veterinary*

Use, 50 F.3d 497, 500 (8th Cir. 1995) (quoting *United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219, 1224 (D. Minn. 1991)). To determine a product's intended use, a court may look to "labeling claims, advertising matter, or oral or written statements" by persons legally responsible for the labeling of the drugs. 21 C.F.R. § 201.128. "Labeling" is defined in the Act as including "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). Written, printed, or graphic matter is considered to have "accompanied" a product as long as it was distributed with the product. *Veterinary Use*, 50 F.3d at 500 (citation omitted).

In this case, the labels attached to Claimant's Chickweed Healing Salve stated "Good for skin disorders. Dry skin, cuts, burns, draws, and poison ivy." (Umscheid Decl. ¶ 5). Additionally, sales pamphlets for Chickweed Healing Salve, which included mail-order forms, contained testimonials about the product, such as:

> I had skin cancer removed 2 times from my face. The 3rd time it came back, I decided to use Chickweed Healing Salve. Within 2 weeks, it was gone. I also used it on my leg and ankle that was swollen. It went down and the soreness left also. Thank you for your help.

(*Id.*).

The information connected with Chickweed Healing Salve communicates that it will treat certain medical issues, such as cancer and rashes. Accordingly, the material attached to and accompanying the Chickweed Healing Salve indicates Claimant intended this product to be used as a drug. *See United States v. An Article . . . Consisting of 216 Individually Cartoned Bottles, More or Less, of an Article Labeled in part: Sudden Change*, 409 F.2d 734, 742 (2d Cir. 1969) (determining that a product was a drug when it claimed to affect the structure of the skin in some physiological way).

The labels attached to To-Mor-Gone state it was a "Black Salve." (Umscheid Decl. ¶ 6). The sales pamphlet accompanying To-Mor-Gone stated it was "Good for Warts, Moles and Tumors." (*Id.*). The sales pamphlet additionally included a testimonial stating:

> I had a mole on the side of my neck. Doctors felt like it could be Cancer and wanted to remove it, but I put on TO-MOR-GONE every day and put a band aid over it. In about 2 ½ weeks it came off, left no scar, never bled. I am thankful to have TO-MOR-GONE.

(*Id.*).

The information connected with To-Mor-Gone communicates that it will treat certain medical issues, such as tumors. Accordingly, the material attached to and accompanying To-Mor-Gone indicates Claimant intended this product to be used as a drug. *See Sudden Change*, 409 F.2d at 742 (determining that a product was a drug when it claimed to affect the structure of the skin in some physiological way).

The label attached to a bottle of R.E.P. stated, "For sinus infection, put on forehead & cheeks. For breath freshener put drop on tongue." (Umscheid Decl. ¶ 7). The labeling did not include a list of ingredients. (*Id.*). The sales pamphlet accompanying R.E.P. stated, "R.E.P. is good for sinus infections, cold symptoms, sore throat, etc…and [was] also an active breath freshener." (*Id.*). Additionally, the sales pamphlet contained testimonials, such as:

> I had a sinus infection for over a year. I was using 3 to 4 nasal spray containers a week. I finally went and got R.E.P. FROM Sam. I applied as he told me to and didn't use a nasal spray. I drained a lot of ugly junk the next day and my sinuses cleared up immediately.

(*Id.*).

The information connected with R.E.P. communicates that it will treat certain medical issues, such as sinus infections and a cold. Accordingly, the material attached to and accompanying R.E.P. indicates Claimant intended this product to be used as a drug. *See United States v. Berst*, No. 6:11-cv-6370-TC, 2012 WL 4361408, at *4-5 (D. Ore. Aug. 2, 2012)

(finding that the products were drugs because they were intended to treat, among other things, colds); *Am. Health Prods. Co. v. Hayes*, 574 F. Supp. 1498, 1501 (S.D.N.Y. 1983) (noting that an orange sold as a cure for the common cold would be considered a drug); *United States v. 22 Devices, more or less, Halox Therapeutic Generator*, 98 F. Supp. 914, 918 (S.D. Cal. 1951) (noting that sinusitis was a disease).

Claimant argues that Chickweed Healing Salve, To-Mor-Gone, and R.E.P. are not drugs as defined in the Act because they were not intended to cure a disease. (Doc. # 71, p. 12). To support his argument, Claimant introduces the dictionary definitions of "disease" as follows:

> an impairment of the normal state of the living animal or plant body or one of its parts that interrupts or modifies the performance of the vital functions, is typically manifested by distinguishing signs and symptoms, and is a response to environmental factors (as malnutrition, industrial hazards, or climate), to specific infective agents (as worms, bacteria, or viruses), to inherent defects of the organism (as generic anomalies), or to combinations of these factors. http://www.merriam-webster.com/medical/disease.
>
> a condition of the living animal or plant body or of one of its parts that impairs normal functioning and is typically manifested by distinguishing signs and symptoms. http://www.merriam-webster.com/dictionary/disease.

(*Id.*).

Claimant's argument is unavailing for at least two (2) reasons. First, cancer, tumors, skin rashes, sinus infections, and colds fit into the definitions of disease as provided by Claimant. Second, a product need not be intended to cure a disease to fit into the definition of a drug as defined in the Act. A product is also a drug if it is "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C). As described in the labeling accompanying the Chickweed Healing Salve, To-Mor-Gone, and R.E.P., those products were intended to affect the structure and function of the body. Accordingly, Claimant's argument is unpersuasive, no genuine issues of material fact remain, and the Government is entitled to judgment as a matter of law on the issue of whether Defendants in rem are drugs.

ii. Whether Defendants in rem are "new"

Under the Act, a drug is considered a "new" drug if it is, "[a]ny drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1). The exclusion of drugs that are generally recognized as safe and effective from the category of "new drugs" is a narrow one. *United States v. Undetermined Quantities of Various Articles of Drug . . . Equidantin Nitrofurantoin Suspension*, 675 F.2d 994, 1000 (8th Cir. 1982) (quoting *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 802 (2d Cir. 1980)).

"'[G]eneral recognition' requires a two-step showing: first, that there is a general recognition in fact, *i.e.*, that there is an expert consensus that the product is effective; and second, that the expert consensus is based upon 'substantial evidence' as defined in the Act and in FDA regulations." *United States v. An Article of Drug Consisting of 4,680 Pails, More or Less, Each Pail Containing 60 Packets, etc.*, 725 F.2d 976, 985 (5th Cir. 1984). "'Substantial evidence' itself embodies two elements – one quantitative and one qualitative." *Id.* "Quantitatively, the studies concerning the product need not be unanimous, or even overwhelming, in their support of the product's effectiveness." *Id.* Instead, the term "substantial" is "'understood to embrace the idea, not of preponderance, but rather of a responsible body of qualified opinion.'" *Id.* (quoting *Hynson, Westcott & Dunning, Inc. v. Richardson*, 461 F.2d 215, 220 (4th Cir. 1972)). "Qualitatively, the studies must be adequate and well-controlled, upon which qualified experts can reasonably conclude that the product is effective for its labeled indications." *Id.* (citation omitted). Further, "an unawareness of the drug product by experts generally or a genuine dispute among qualified experts regarding a drug product's safety and effectiveness precludes its

qualifying for exclusion as generally recognized." *Veterinary Use*, 50 F.3d at 501 (quoting *Premo Pharm.*, 629 F.2d at 803) (internal quotation marks and other punctuation omitted).

In this case, Dr. Lee, attested that there were no published adequate and well-controlled studies of any kind concerning Chickweed Healing Salve, To-Mor-Gone, or R.E.P. (Lee Decl. ¶ 19). Dr. Lee further attested that, in his opinion, Defendants in rem were not generally recognized as safe and effective. (*Id.* ¶ 20). Because there were no adequate and well-controlled studies, there is neither qualitative nor quantitative evidence showing that Defendants in rem are generally recognized as safe and effective. Therefore, Defendants in rem are not generally recognized as safe and effective and accordingly do not fit within the exception and are "new drugs" as defined under the statute.

Claimant argues Chickweed Healing Salve is generally recognized as safe and effective and therefore is not a new drug. (Doc. # 71, p. 15). In support of his contention, Claimant points to the declaration of Dr. Chen. Dr. Chen stated in a report that:

> Nevertheless, all the individual herbs in Chickweed Healing Salve have previous human use and several are also considered to be spices or food items, such as chickweed, mint, rosemary, and lavender. These plants are generally safe when used moderately in raw herb forms. Concentrated extracts or essential oils could be toxic even at much lower doses than the herb themselves.

(Shaw Decl., Ex. B, p. 6). Claimant additionally points to statements he made in an affirmation that his products "[were] simply raw materials [mixed] by cold infusion together with no chemical additives of any kind." (Girod Affirm. ¶ 6).

The fact that the components of Chickweed Healing Salve are generally safe when used in their raw herb forms and that Chickweed Healing Salve consists of only raw materials does not raise a genuine issue of material fact concerning the general recognition of that drug's safety and effectiveness. Instead, the only evidence in the Record indicates that there is no expert consensus regarding the safety and effectiveness of Defendants in rem. Accordingly, the

Government is entitled to judgment as a matter of law on the issue of whether Defendants in rem are new drugs.

iii. Whether Defendants in rem are "unapproved"

Dr. Lee attested that there were no FDA-approved drug applications for Defendants in rem. (Lee Decl. ¶ 22). Further, Claimant admitted in his Suggestions in Opposition to the Government's Motion that he has not submitted an application to the FDA concerning Defendants in rem. (Doc. # 71, p. 11). Accordingly, Defendants in rem are not FDA-approved and are, therefore, "unapproved." The Government is entitled to judgment as a matter of law on this issue.

2. Misbranded Drugs

The Government alleges Defendants in rem are misbranded under several provisions of the Act: 21 U.S.C. §§ 352(f)(1), (f)(2), (j), and (e)(1)(A).

i. 21 U.S.C. § 352(f)(1)

A drug is misbranded under § 352(f)(1) unless its labeling contains "adequate directions for use." Adequate directions for use are those directions "under which the layman can use a drug safely and for the purposes of which it is intended." 21 C.F.R. § 201.5. In this case, no expert consensus exists regarding the safety and effectiveness of Defendants in rem; thus, the purpose for which Defendants in rem should be intended cannot be ascertained. Additionally, for that reason, the proper instructions concerning drug safety cannot be ascertained. Because the safety and purpose of Defendants in rem has not been determined, it would be impossible to write adequate directions for use as required by 21 U.S.C. § 352(f)(1). *See United States v. Undetermined Quantities of Articles of Drug,* 145 F. Supp. 2d 692, 702 (D. Md. 2001) ("Essentially, in the absence of investigations or clinical data demonstrating the safety and

efficacy of the drugs, there can be no adequate instruction for their *safe* use." (citing *United States v. Article Consisting of 46 Devices, "Dynatone,"* 315 F. Supp. 588, 591 (D. Minn. 1970))). Because Defendants in rem do not contain adequate directions for use, they are misbranded under § 352(f)(1).

ii. 21 U.S.C. § 352(f)(2)

The Government argues To-Mor-Gone is also misbranded under § 352(f)(2).[1] Section 352(f)(2) requires that drug labeling contain "such adequate warnings against use in those pathological conditions . . . where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application." The Government argues To-Mor-Gone does not contain adequate warnings because it did not warn about the dangers of "Black Salves" and bloodroot, a listed ingredient of To-Mor-Gone. (Doc. # 51, p. 20).

According to Dr. Liedtka, the term "Black Salve" refers to "a number of different compounds containing escharotic (caustic) agents as their primary ingredients." (Liedtka Decl. ¶ 13). Dr. Liedtka further attested that "escharotic agents like black salves are caustic, corrosive substances that produce a thick coagulated crust (an eschar) and subsequently a scar on the area to which the escharotic agent(s) is applied." (*Id.* ¶ 15). Case reports show that scarring caused by escharotic agents masked the recurrence of skin cancer, causing delay in treatment and

[1] The Government additionally asserts Chickweed Healing Salve is misbranded under § 352(f)(2) because it did not bear adequate warnings about the health risks of comfrey, an ingredient in Chickweed Healing Salve. (Doc. # 51, p. 19). According to the Government, comfrey contains "pyrrolizidine alkaloids," which are harmful to humans. (*Id.*). The Government is not entitled to judgment as a matter of law on that issue because Claimant introduced evidence that the comfrey found in Chickweed Healing Salve did not contain pyrrolizidine alkaloids, which may preclude the need for any warning concerning their toxicity. (Doc. # 71, Ex. A Phytochemical Services, Incorporated Test Results). However, because the Court determines that Chickweed Healing Salve should be condemned under other portions of the Act, as explained throughout this Order, the factual dispute concerning the toxicity of the comfrey found in Chickweed Healing Salve is not material.

appropriate therapy, and, in at least one (1) case, death. (*Id.* ¶ 16). An additional risk associated with escharotic agents is the destruction of normal tissue surrounding the treated area. (*Id.* ¶ 17). In some cases, "the topical application of escharotic agents to treat skin cancer has resulted in the complete loss of the nasal ala (area of the external nose that surrounds the nostril) or mutilation of tissue to the point of bone exposure." (*Id.*).

Notwithstanding the above-listed health risks, To-Mor-Gone's labeling did not contain any warnings. Accordingly, it does not contain adequate warnings as required by 21 U.S.C. § 352(f)(2). The Government is entitled to judgment as a matter of law as to this issue.

iii. 21 U.S.C. § 352(j)

The Government further argues that To-Mor-Gone is misbranded within the meaning of 21 U.S.C. § 352(j).[2] Under § 352(j), a drug is misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." Dr. Liedtka attested that topical application of To-Mor-Gone "could result in scarring and/or mutilation of the area to which the product is applied." (Liedtka Decl. ¶ 19). Accordingly, To-Mor-Gone is dangerous to health under § 352(j) and is misbranded. The Government is entitled to judgment as a matter of law.

iv. 21 U.S.C. § 352(e)(1)(A)

The Government's final argument concerning misbranding is that R.E.P. was misbranded under § 352(e)(1)(A). Under § 352(e)(1)(A)(ii), a drug is misbranded unless the label contains a list of each active ingredient. The labeling for R.E.P. failed to list any ingredients, whether

[2] The Government additionally argues Chickweed Healing Salve is misbranded under § 352(j) because comfrey that is topically applied is potentially dangerous. (Doc. # 51, p. 21). For the same reasons as explained in the Court's previous footnote, the Government is not entitled to judgment as a matter of law on this issue, but this factual dispute is not material.

active or inactive. (Umscheid Decl. ¶ 7). Therefore, R.E.P. is misbranded under § 352(e)(1)(A) and the Government is entitled to judgment as a matter of law on this issue.

3. Interstate Commerce

Twenty-one U.S.C. § 334 provides for the condemnation of drugs that are misbranded or unapproved new drugs "when introduced into or while in interstate commerce" or "while held for sale . . . after shipment in interstate commerce." § 334(a)(1). The "held for sale" requirement is interpreted broadly. *See Hipolite Egg Co. v. United States*, 220 U.S. 45, 54 (1911) (holding that products not intended for personal consumption are "held for sale"). Further, the requirement is satisfied "even when only an ingredient is transported interstate." *Baker v. United States*, 932 F.2d 813, 814 (9th Cir. 1991).

In this case, the requirement of interstate commerce is satisfied. Claimant's manufacturing operation was located at his residence in Owingsville, Kentucky and the Government seized Defendants in rem in Bogard, Missouri. (Parmon Decl. ¶ 3; Umscheid Decl. ¶ 10). Moreover, Claimant bought raw ingredients in interstate commerce, including beeswax from West Babylon, New York, and rosemary, eucalyptus, peppermint, and lavender from Mishawaka, Indiana. (Parmon Decl. ¶ 14). Further, Claimant did not deny that his products were introduced into interstate commerce but instead maintained "that neither his products, nor any of their components [were] drugs that [were] prohibited from being shipped in interstate commerce." (Doc. # 71, p. 7). Because the requirement for interstate commerce was met, Defendants in rem are liable for condemnation pursuant to 21 U.S.C. § 334(a).

B. Injunctive Relief against Claimant

Twenty-one U.S.C. § 332 gives district courts jurisdiction to enjoin violations of the Act. 21 U.S.C. § 332(a). Injunctive relief is "routinely awarded." *United States v. Syntrax*

Innovations, Inc., 149 F. Supp. 2d 880, 884 (E.D. Mo. 2001) (citing cases). In this statutory context, "[a] district court may issue an injunction if it concludes that the injunction is necessary to prevent future violations." *United States v. Articles of Drug*, 825 F.2d 1238, 1248 (8th Cir. 1987) (citation omitted). Accordingly, it is not required that the government show irreparable harm. *See United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 28 (2d Cir. 1972) ("No specific or immediate showing of the precise way in which violation of the law will result in public harm is required." (citing *Shafer v. United States*, 229 F.2d 124 (4th Cir. 1956)) (additional citations omitted)). "Good faith is not a defense to the issuance of an injunction." *Articles of Drug*, 825 F.2d at 1248 (citation omitted). "Nor may a defendant successfully defend against the issuance of an injunction by asserting that the injunction would drive it out of business." *Id.* (citation omitted).

As explained above, Defendants in rem are misbranded or unapproved new drugs as prohibited by the Act. Accordingly, Claimant violated the Act and the Court has jurisdiction to enjoin Claimant under § 332. If the Court determines that an injunction is necessary to prevent future violations it may thus enter an injunction. After considering the evidence in a light most favorable to Defendants in rem and Claimant, the Court determines that Claimant is likely to continue to violate the Act unless he is enjoined. Claimant was aware that his conduct violated the Act. At least three (3) times in the past twelve (12) years, FDA officials warned Claimant that his products violated the Act. (Parmon Decl. ¶¶ 8, 11, 13). The Court recognizes that Claimant slightly modified the labeling of Defendants in rem in an attempt to conform with the

Act; however, despite these minor adjustments, Defendants in rem continue to violate the Act. Accordingly, injunction is appropriate under 21 U.S.C. § 332(a).[3]

CONCLUSION

Condemnation of Defendants in rem is proper because they are unapproved new drugs or misbranded drugs under the Act. Further, the requirement of interstate commerce is satisfied. Finally, an injunction is appropriate because future violations of the Act are likely unless Claimant is enjoined. Accordingly, for these reasons and the reasons set forth above, it is

ORDERED the Government's Motion is GRANTED.[4]

IT IS FURTHER ORDERED

1. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all parties to this action. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1395.
2. Defendants in rem are articles of drug within the meaning of 21 U.S.C. § 321(g), in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and may not be introduced or delivered into interstate

[3] The Government requests that the injunction include language requiring Claimant to hire an FDA label expert. (Doc. # 51, p. 28). However, the Government does not provide any reason such an expert is necessary or even appropriate. Further, after a review of relevant case precedent, the Court could not find an example of another court requiring the retention of a label expert. Accordingly, the Court declines to include that language in the injunction.

[4] Because of the Court's present Order, Claimant's pending counterclaims are now moot. In Claimant's Answer to Government's Amended Complaint (Doc. # 37), Claimant alleged, as both Affirmative Defenses and as Counterclaims, the Government violated the First and Fourth Amendment of the United States Constitution. Granting Government's present Motion for Summary Judgment necessarily determines there is no genuine issue of material fact regarding Claimant's First and Fourth Amendment allegations. Therefore Government's Motion for Summary Judgment as to Claimant's Fourth and Fifth Counterclaims (Doc. # 72) is also GRANTED.

commerce under 21 U.S.C. § 355(a) because they are "new drugs" within the meaning of 21 U.S.C. § 321(p) and no approvals of applications were filed under 21 U.S.C. §§ 355(b) or (j) or exemptions from such requirements under 21 U.S.C. § 355(i) are in effect for such drugs.

3. Defendants in rem are misbranded while held for sale after shipment of one (1) or more of their components in interstate commerce within the meaning of the Act, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use and they are not exempt from such requirement under 21 C.F.R. § 201.115 because the articles are unapproved new drugs.
4. To-Mor-Gone is additionally misbranded within the meaning of the Act, 21 U.S.C. § 352(f)(2), in that it fails to bear adequate warnings about the risks of toxicity and allergic reactions in consumers who are sensitive to certain ingredients contained in such articles.
5. To-Mor-Gone is further misbranded within the meaning of the Act, 21 U.S.C. § 352(j), in that it is dangerous to health when used in the manner, frequency, or duration recommended or suggested by its labeling.
6. R.E.P. is misbranded within the meaning of the Act, 21 U.S.C. § 352(e)(1)(A), in that its labeling does not contain any ingredient information.
7. Defendants in rem are, therefore, condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.
8. Claimant shall pay to the Government all court costs and fees, and storage and other proper expenses pursuant to 21 U.S.C. § 334(e). Claimant shall pay these costs within twenty-one (21) business days after receiving notice of such costs from the

FDA, the United States Marshals Service ("USMS"), or the United States Department of Justice ("DOJ").

9. Pursuant to 21 U.S.C. § 334(d)(1), and within twenty-one (21) days of the entry of this Order, Claimant shall execute and file with the Clerk of this Court a good and sufficient bond in the amount of $10,000 to be applied to Defendants in rem. The bond shall be in a form acceptable to the Clerk of this Court and payable to the United States of America and conditioned on Claimant not selling or disposing of Defendants in rem contrary to the provisions of this chapter or the laws of any State or Territory in which it is sold.

10. Pursuant to § 334(d)(1), and within twenty (20) days after filing the bond pursuant to Paragraph 9, Claimant shall give written notice to the FDA that, at his own expense and under FDA's supervision, Claimant is prepared to destroy Defendants in rem. Claimant's notice shall specify the proposed time, place, and method of destruction of Defendants in rem.

11. Claimant shall not destroy Defendants in rem until Claimant has received written authorization from the FDA to commence destruction.

12. Following Claimant's payment of costs and posting of the bond, as required by Paragraphs 8 and 9 of this Order, the USMS, upon notice from the FDA that Claimant is authorized to commence destroying Defendants in rem, will release Defendants in rem to Claimant's custody. Defendants in rem shall be released solely for Claimant to destroy them in compliance with the destruction plan described in Paragraph 10 and under FDA supervision.

13. Within twenty (20) business days of receiving written authorization to commence destroying Defendants in rem, Claimant shall complete the destruction of Defendants in rem in compliance with this Order. Claimant shall pay all reasonable costs of the FDA's supervision of the destruction within twenty-one (21) business days of receiving notice of such costs from the FDA.

14. Claimant shall at all times, until all Defendants in rem have been destroyed pursuant to Paragraph 13, retain Defendants in rem in his custody for examination or inspection by the FDA in a place made known to and approved by the FDA and shall maintain all records or other proof necessary to establish the identity of the articles to the FDA's satisfaction.

15. Claimant shall not cause Defendants in rem to be disposed of in a manner contrary to the Act or other laws of the United States or of any State or Territory in which they are disposed.

16. If Claimant breaches any condition of this Order concerning the destruction of Defendants in rem, Claimant shall, at his own expense, immediately return to the USMS all Defendants in rem in his custody that have been released pursuant to Paragraph 12. Following return of Defendants in rem, the USMS shall destroy Defendants in rem and make due return to this Court regarding their disposition. In the event that return of any Defendants in rem becomes necessary under this Paragraph, Claimant shall be responsible for all costs of storage and disposition incurred by the Government.

17. If Claimant does not repossess and destroy Defendants in rem in the manner described in this Order, or if any portion of Defendants in rem remains in the USMS's

custody after expiration of the twenty (20) day period described in Paragraph 13, the USMS will destroy Defendants in rem and make due return to this Court regarding their disposition. Claimant shall bear the costs of storage and destruction that are incurred by the Government pursuant to this Paragraph and shall pay such costs within twenty-one (21) business days after receiving an invoice from the FDA, the USMS, or the DOJ.

18. Pursuant to § 334(d)(1), if Claimant fails to destroy Defendants in rem as required by this Order, then, on the motion of the Government in this proceeding, the bond shall be forfeited in its entirety to the Government and judgment entered thereon in favor of the Government.

19. The DOJ, upon being advised by the FDA that Defendants in rem have been destroyed in compliance with this Order and that Claimant has paid all costs as of that date in accordance with Paragraphs 8 and 13, will transmit such information within sixty (60) days to the Clerk of this Court, whereupon the bond given in this proceeding shall be returned to Claimant.

20. Upon entry of this Order, Claimant and each and all of his agents, employees, representatives, successors, assigns, and any and all persons in active concert or participation with any of them who receive notice of this Order (collectively "Associated Persons"), are hereby permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

    a. violates 21 U.S.C. § 331(d) and results in the introduction or delivery for introduction into interstate commerce new drugs, as defined by 21 U.S.C. §

321(p) that are neither approved pursuant to 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

b. violates 21 U.S.C. § 331(a) and results in the introduction or delivery for introduction into interstate commerce articles of drug that are misbranded; or

c. violates 21 U.S.C. § 331(k) and results in an article of drug becoming misbranded while held for sale after shipment of one (1) or more components in interstate commerce.

21. Upon entry of this Order, Claimant and each and all Associated Persons who receive notice of this Order, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from manufacturing, processing, packaging, labeling, holding, selling, or distributing Defendants in rem, or any product labeled as or being similar in its composition or effect to such products, or any other product that is a new drug as defined by 21 U.S.C. § 321(p), unless and until:

a. Claimant removes all claims that cause Defendants in rem to be drugs within the meaning of the Act from his products, labels, labeling, promotional materials, and websites owned or controlled by Claimant;

b. Claimant ensures none of his products intended for human use contain extracts or components of bloodroot plant (*Sanguiniaria Canadensis*), and Claimant provides written certification to the FDA that Claimant's products intended for human use do not contain such ingredients or any ingredients similar in their composition or effect to such ingredients;

c. the FDA, as is proper under the Act and all applicable regulations and as it deems necessary, conducts inspections of Claimant's facility, including the

buildings, equipment, all articles of drug, and relevant records contained therein; and

d. the FDA notifies Claimant in writing that Claimant appears to be in compliance with the requirements of this Paragraph. If Claimant appears to be in compliance with the requirements of this Paragraph, the FDA must notify Claimant of such fact within thirty (30) days. In no circumstance shall the FDA's silence be construed as a substitute for written notification.

22. Paragraph 21 shall not apply to any drugs subject to an approved new drug application or an approved abbreviated new drug application held by Claimant and filed with the FDA pursuant to 21 U.S.C. § 355; or drugs for which an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect.

23. Upon entry of this Order, and for five (5) years after its entry, if at any time the FDA reasonably determines, based on the results of an inspection; the analysis of a sample or report; data prepared or submitted by Claimant; or any other information, that Claimant has failed to comply with the provisions of this Order; has violated the Act or its implementing regulations; or that additional corrective actions are necessary to achieve compliance with this Order, the Act, or its implementing regulations, the FDA may, as and when it reasonably deems necessary, notify Claimant in writing of the noncompliance and order Claimant to take appropriate corrective action, including, but not limited to, ordering Claimant to immediately take any of the following actions:

a. cease manufacturing, preparing, packing, labeling, holding or distributing any or all drugs;

b. recall, at Claimant's expense, any drug products that are adulterated, misbranded, unapproved, or otherwise in violation of this Order, the Act, or its implementing regulations;

c. revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Order;

d. submit additional reports or information to the FDA as reasonably requested;

e. issue a safety alert;

f. pay liquidated damages as detailed in Paragraph 33; or

g. take any other corrective action as the FDA reasonably deems necessary to bring Claimant into compliance with this Order, the Act, or its implementing regulations.

The provisions of this Paragraph shall be apart from, and in addition to, all other remedies available to the FDA.

24. Upon receipt of any order issued by the FDA pursuant to Paragraph 23, Claimant shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 23 shall continue until Claimant receives written notification from the FDA that Claimant appears to be in compliance with this Order, the Act, and its implementing regulations and that Claimant may, therefore, resume operations. Such written notification will issue from the FDA within thirty (30) business days from the date the FDA determines Claimant appears to be in compliance.

25. For five (5) years after the entry of this Order, the FDA shall be permitted, without prior notice and when the FDA reasonably deems necessary, to make reasonable inspections of Claimant's facility and, without prior notice, take any other reasonable measures to monitor and ensure continuing compliance with the terms of this Order, the Act, and FDA regulations. During inspections of Claimant's facility, the FDA shall be permitted to have reasonable and immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other material therein; take photographs and make video recordings; take samples of Claimant's raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other material; and examine and copy all records relating to the manufacture, preparing, packing, labeling, holding, and distribution of any and all drugs, and their respective components. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

26. Claimant shall reimburse the Government for any reasonable costs of supervising Claimant's destruction of Defendants in rem and for reasonable costs associated with inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Order, at the standard rates prevailing at the time the activities are accomplished. As of the date of this Order, the rates are $87.57 per hour or fraction thereof per representative for supervision other than laboratory and analytical work; $104.96 per hour or fraction thereof per representative for laboratory and analytical work; and $.565 per mile for travel expenses for travel by automobile; government rate or the equivalent for reasonable travel by air or other means; and the published government

per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where reasonable and necessary. In the event that the standard rates generally applicable to the FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

27. Within ten (10) business days after entry of this Order, Claimant shall post a copy of this Order in a common area at his facility and at any other location at which Claimant conducts business and shall ensure the Order remains posted for as long as the Order remains in effect.

28. Within ten (10) business days after entry of this Order, Claimant shall provide a copy of the Order by personal service or certified mail (restricted delivery, return receipt requested) to each Associated Person. Within twenty (20) business days after entry of this Order, Claimant shall provide to the FDA an affidavit stating the fact and manner of Claimant's compliance with this Paragraph and identify the names, addresses, and positions of all persons who have received a copy of this Order.

29. In the event Claimant becomes associated with any additional Associated Person for five (5) years after entry of this Order, Claimant shall immediately provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person. Each time Claimant becomes associated with an Associated Person, Claimant shall, within ten (10) business days, provide to the FDA an affidavit stating the fact and manner of his compliance with this Paragraph and identifying the names and positions of all Associated Persons who received a copy of this Order pursuant to this paragraph. Within ten (10) business days of

receiving a reasonable request from the FDA for any information or documentation that the FDA deems necessary to evaluate Claimant's compliance with this Paragraph, Claimant shall provide such information or documentation to the FDA.

30. Claimant shall notify the FDA in writing at least ten (10) business days before any change in ownership, name, or character of his business that occurs within ten (10) years after entry of this Order, including incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Samuel Girod d/b/a S.A.E.G., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Order. Claimant shall provide a copy of this Order to any prospective successor or assign at least twenty (20) business days before any sale or assignment. Claimant shall furnish the FDA with an affidavit of compliance with this Paragraph no later than ten (10) business days before such assignment or change in ownership.

31. Claimant shall abide by the decisions of the FDA and its representatives, which shall be final, as required by law and this Order. All decisions specified in this Order shall be vested in the FDA's legal discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A) or other lawful standard. Review by a court and discovery procedures shall be conducted according to applicable law.

32. All notifications, correspondence, and communications to the FDA required by the terms of this Order shall reference this civil action, be prominently marked "Samuel Girod d/b/a S.A.E.G.," and be addressed to:

District Director
Kansas City District Office
U.S. Food and Drug Administration
Department of Health and Human Services
11510 West 80th Street
Lenexa, KS 66214

33. Should Claimant fail to comply with any provision of this Order, the Act, or its implementing regulations, Claimant shall pay to the Government the sum of $200 in liquidated damages for each business day such violation continues and an additional sum of $100 in liquidated damages for each violation of this Order, the Act, or its implementing regulations (for example, if two (2) violations occurs for two (2) business days, the liquidated damages shall be $600), and an additional sum equal to the retail value of each shipment of an unapproved new drug or misbranded drug in liquidated damages for each unlawful shipment. The liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the Government to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of liquidated damages.

34. Should the Government bring, and prevail in, a contempt action to enforce the terms of this Order, Claimant shall, in addition to other remedies, reimburse the Government for its reasonable attorneys' fees and overhead, investigational and analytical experts, expert witness fees, travel expenses incurred by attorneys and witnesses, administrative court costs, and any other reasonable costs or fees relating to such proceedings.

35. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

s/ Gary A. Fenner
GARY A. FENNER, JUDGE
UNITED STATES DISTRICT COURT

DATED: September 17, 2013